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09/913,752	11/21/2001	Darja Fercej Temeljotov	033248-017	5309

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/913,752	Applicant(s) FERCEJ TEMELJOTOV ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination and Amendments/Remarks received on September 17, 2003 is acknowledged. Claims **16-34** are pending in this application. Claims 1-15 stands cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims recite, "wherein the hydrophilic component comprises about 15-18 weight percent of the formulation." This is vague and indefinite since the recitation "hydrophilic component" is a broad term and it is unclear what exactly the applicant intends to limit this component to. For instance, conventional excipients are termed hydrophilic, however in the exemplified embodiments applicant excludes these as the "hydrophilic component". Example 3 contains HPMC and lactose, which are both hydrophilic components and renders the component outside of applicant's claimed range. Therefore, the metes and bounds of this term is vague to one of ordinary skill in the art since applicant is using it to include certain components and exclude others. If applicant intends to only limit the hydrophilic components to the components on page 6 of instant specification and not all hydrophilic excipients, i.e. lactose, then it is suggested that applicant restructures the claim containing a Markush group of the components on page 6. For examination purposes, the claims will be interpreted as the composition containing

any hydrophilic component in the given range. Since the claims are open-ended, they can also include other hydrophilic components.

Claim 32 recites "fatty alcohol" as part of the hydrophilic component Markush group. It is unclear how all fatty alcohols are considered hydrophilic. For instance, higher fatty alcohols such as cetyl and stearyl alcohol are lipophilic. Therefore, the metes and bounds of this term is vague to one of ordinary skill in the art.

Claim 32 recites "large specific surface absorbents" as part of the hydrophilic component Markush group. This is vague and indefinite since it is unclear what components are being claimed by this terminology. Further, the term "large" is a relative term.

Claim 25 recites "characterized in that the tablet is lacquered." This is vague since it is unclear what the exact limitation of this claim is. How can a tablet be lacquered? Is applicant defining the coating of the tablet? It should be noted that a coating on a tablet provides a lacquered finish to a tablet but a tablet itself cannot be lacquered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 24, 29-30, and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 5,707,646 to Yajima et al.

Yajima et al disclose taste masking pharmaceutical compositions in the form of tablets, capsules, dry powders, and syrup. See column 3, lines 47-50. Yajima et al teach a taste-masking

polymer in a low-melting substance, which is in a concentration of 10-70%. The polymer is Eudragit E and the low-melting substance includes paraffin, wax, hydrogenated oil, palmitic acid, stearic acid, stearyl alcohol, sorbitan fatty esters, and glycerin fatty esters, etc. see column 2, line 45 to column 3, line 5. Yajima et al teach the use of excipients, binders such as hydroxypropylmethyl cellulose (HPMC), polyvinyl pyrrolidone, gelatin, ethyl cellulose, etc., lubricants, surfactants, and coating agents. Example 6 disclose 600g (19.98%) of stearyl alcohol (fatty component), 100g Eudragit, 300g (10%) clarithromycin, 400g (40%) sorbitol, 229g (22.9%) xylitol, 100g (10%) maltitol, 20g (2%) magnesium oxide, 14g (1.4%) starch, 20g hydroxypropyl cellulose (2%), and 10g (1%)of sodium carboxymethyl cellulose, and 3g saccharin. Example 4 and 7 disclose the use of glyceryl monostearate.

Note that the prior art reads on the instant claims since the claims only require that there the hydrophilic component in the instant weight percentage; however since the claims have open claim language, the claims can include other hydrophilic excipients. Therefore, Yajima et al disclose in example 6, one fatty component in the instant amount, i.e. stearyl alcohol in the amount of 19.98% and one hydrophilic component in the instant amount, i.e. maltitol in the amount of 10%. The instant claim language can include other hydrophilic components.

Note that since the prior art teaches the instant ratio of claim 29 and the composition is not structurally different, the two compositions will behave in the same manner. If applicant asserts that the instant claims and the prior art do not behave in a similar manner, then applicant is required to structurally distinguish the claims.

Claims 16, 19, 24, and 27-33 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/22319 to Briskin et al.

Briskin discloses an oral composition containing 43.4% clarithromycin, 5.5% povidone, 26% carbopol, 5% hydroxypropyl cellulose, 10% glyceryl behenate, and 10% microcrystalline cellulose. See table 1 on page 8. the composition is then formulated in to a tablet or capsule. See page 7, line 7. On page 6, the method of making the tablet is disclosed wherein the particles are sieved before compressing the tablets.

Note that the prior art reads on the instant claims since the claims only require that there the hydrophilic component in the instant weight percentage; however since the claims have open claim language, the claims can include other hydrophilic excipients. Therefore, Briskin et al disclose one fatty component in the instant amount, i.e. glyceryl behenate in the amount of 10% and one hydrophilic component in the instant amount, i.e. hydroxypropyl cellulose in the amount of 5%. The instant claim language can include other hydrophilic components.

Note that since the prior art teaches the instant ratio of claim 29 and the composition is not structurally different, the two compositions will behave in the same manner. If applicant asserts that the instant claims and the prior art do not behave in a similar manner, then applicant is required to structurally distinguish the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-18, 20-21, 23, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yajima et al.

Yajima et al disclose taste masking pharmaceutical compositions in the form of tablets, capsules, dry powders, and syrup. See column 3, lines 47-50. Yajima et al teach a taste-masking polymer in a low-melting substance, which is in a concentration of 10-70%. The polymer is Eudragit E and the low-melting substance includes paraffin, wax, hydrogenated oil, palmitic acid, stearic acid, stearyl alcohol, sorbitan fatty esters, and glycerin fatty esters, etc. see column 2, line 45 to column 3, line 5. Yajima et al teach the use of excipients, binders such as various cellulose derivatives such as hydroxypropylmethyl cellulose (HPMC), polyvinyl pyrrolidone, gelatin, ethyl cellulose, etc., lubricants, surfactants, and coating agents. Disintegrants such as low substituted hydroxypropyl cellulose, carboxymethyl cellulose, sodium carboxymethyl cellulose, etc. see column 3, lines 60-65. Coating agents include hydroxypropylmethyl cellulose, hydroxypropyl cellulose, methylcellulose, hydroxymethylcellulose phthalate, shellac, etc. see column 4, lines 20-26. Example 6 disclose 600g (19.98%) of stearyl alcohol (fatty component), 100g Eudragit, 300g (10%) clarithromycin, 400g (40%) sorbitol, 229g (22.9%) xylitol, 100g (10%) maltitol, 20g (2%) magnesium oxide, 14g (1.4%) starch, 20g hydroxypropyl cellulose

(2%), and 10g (1%)of sodium carboxymethyl cellulose, and 3g saccharin. Example 4 and 7 disclose the use of glyceryl monostearate.

Although, Yajima et al teach the suitability of low substituted hydroxypropyl cellulose, the reference does not specify a low substituted hydroxypropyl methylcellulose. Further, the reference does not specify the step of compressing the mixture to form a tablet.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Yajima et al and utilize instant low substituted hydroxypropyl methylcellulose. One would be motivated to do so since Yajima et al teach the use of low substituted celluloses as suitable disintegrators. Therefore, it is prima facie obvious to utilize substitute one conventional additive for another. Furthermore, the step of compressing the mixture into a tablet form and the use of a buffer agent is prima facie obvious to one of ordinary skill in the art since these are conventional techniques and additives routinely utilized in the pharmaceutical art. Lastly, Yajima teaches several types of coating for the tablet and depending on the intended use of the tablet, one would be motivated to select accordingly.

Claims 16-18 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,117,452 to Ahlgren et al.

Ahlgren et al teach a composition containing active agents and certain fatty acid combinations. See abstract. The general formula contains 65-90% active agent, 10-25% glyceryl monostearate (the lipophilic component), 2-6% PEG (32) glyceryl palmitostearate (the hydrophilic component), and 1-4% surfactant or emulsifier. Clarithromycin is taught among the suitable active agents. See column 3, line 64. The optional surfactant and emulsifier taught are sodium lauryl sulfate, TWEE or Poloaxmer. See column 6, lines 18-20. The orally ingestible

units are formulated into tablets, pills, capsules, or suspensions. See column 6, lines 28-29. Controlled release coating such as enteric release and sustained release are taught. The amount of coating depends on the function of the coating. See column 6, lines 45-52. The method of making the formulations are discussed wherein the microspheres are sieved prior to forming a tablet. See examples. Note that since the prior art teaches the instant ratio of claim 29 and the composition is not structurally different, the two compositions will behave in the same manner. If applicant claims that the instant claims and the prior art do not behave in a similar manner, then applicant is required to structurally distinguish the claims.

Ahlgren et al do not exemplify clarithromycin.

Although clarithromycin is not exemplified, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Ahlgren et al and include instant clarithromycin as the active ingredient. One would have bee motivated to do so since the reference teaches the instant active as a suitable agent. Therefore, the selection of the active agent is dependent on the symptoms and disease to be treated, which is within the skill of an ordinary artisan.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,117,452 to Ahlgren et al in view of Gibson et al (5811120).

Ahlgren et al teach a composition containing active agents and certain fatty acid combinations. See abstract. The general formula contains 65-90% active agent, 10-25% glyceryl monostearate (the lipophilic component), 2-6% PEG (32) glyceryl palmitostearate (the hydrophilic component), and 1-4% surfactant or emulsifier. Clarithromycin is taught among the suitable active agents. See column 3, line 64. The optional surfactant and emulsifier taught are

sodium lauryl sulfate, TWEE or Poloaxmer. See column 6, lines 18-20. The orally ingestible units are formulated into tablets, pills, capsules, or suspensions. See column 6, lines 28-29. Controlled release coating such as enteric release and sustained release are taught. The amount of coating depends on the function of the coating. See column 6, lines 45-52. The method of making the formulations are discussed wherein the microspheres are sieved prior to forming a tablet. See examples.

The reference does not teach the instant surfactant.

Gibson et al teach pharmaceutical formulations containing raloxifene. Gibson et al teaches the conventional additives in pharmaceutical formulations such as hydrophilic binders (HPMC), surfactants (sodium docosate or sodium lauryl sulfate), and lubricants (glyceryl behenate) (col. 3, line 51 to col. 4, line 26). Further, the reference teaches that the preparation of the oral formulations is well known in the art such as direct compression. The process includes mixing the active with the hydrophilic binder and surfactant, which is then, milled if necessary, drying the granules, and compressing into tablets (col. 5, lines 10-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Ahlgren et al and Gibson et al and substitute Ahlgrens' sodium lauryl sulfate with instant sodium docusate. One would be motivated to do so since Gibson teaches the functional equivalency of sodium docusate and sodium lauryl sulfate as surfactants in pharmaceutical compositions. Therefore, it is prima facie obvious for one of ordinary skill to substitute functional equivalents with the expectation of similar results since the art establishes the functional equivalency of both .

Claims 17-18, 20-24, 26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/22319 to Briskin et al in view of Gibson et al (5811120).

Briskin discloses an oral composition containing 43.4% clarithromycin, 5.5% povidone, 26% carbopol, 5% hydroxypropyl cellulose, 10% glyceryl behenate, and 10% microcrystalline cellulose. See table 1 on page 8. the composition is then formulated in to a tablet or capsule. See page 7, line 7. On page 6, the method of making the tablet is disclosed wherein the particles are sieved before compressing the tablets. A coating may be used to provide controlled release. See page 5.

Briskin et al do not specify the use of hydroxypropyl methylcellulose. Further, Briskin does not teach instant surfactant.

Gibson et al teach pharmaceutical formulations containing raloxifene. Gibson et al teaches the conventional additives in pharmaceutical formulations such as hydrophilic binders selected from cellulose derivatives such as hydroxypropyl methyl cellulose or hydroxypropyl cellulose or carboxymethyl cellulose), surfactants (sodium docosate), and lubricants (glyceryl behenate) (col. 3, line 51 to col. 4, line 26). Further, the reference teaches that the preparation of the oral formulations is well known in the art such as direct compression. The process includes mixing the active with the hydrophilic binder and surfactant, which is then, milled if necessary, drying the granules, and compressing into tablets (col. 5, lines 10-15).

It would have been obvious of one of ordinary skill in the art at the time the invention was made to combine the teachings of Briskin et al and Gibson et al and utilize the instant additives. One would have been motivated to substitute Briskin's cellulose derivative for instant cellulose derivative with the expectation of similar results since Gibson teaches that both are

conventional hydrophilic binders utilized in pharmaceutical compositions. Therefore, it is prima facie obvious for one of ordinary skill to substitute functional equivalents with the expectation of similar results since the art establishes the functional equivalency of both. Furthermore, Gibson teaches the conventional use of surfactants such as instant sodium docusate in pharmaceutical compositions. Thus, the use of conventional additives in the preparation of pharmaceuticals is prima facie obvious.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
PRIMARY EXAMINER

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG